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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,451	11/28/2003	Joel Bougaret	3493-0126P	9996

2292 7590 01/18/2007
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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	01/18/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/18/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/722,451	BOUGARET ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *7-17,20-31 and 35-43* is/are withdrawn from consideration.

5)☒ Claim(s) *32-34* is/are allowed.

6)☒ Claim(s) *1-6,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/13/2004,7/15/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I in the reply filed on 12/6/2006 is acknowledged. The traversal is on the ground(s) that the polymorphs of forms I, II, III, IV and V are not different. This is not found persuasive because each polymorph has its own X-ray diffraction spectrum comprising different characteristic peaks; therefore, each polymorph form would present an undue burden of search on the Examiner. Furthermore, as is stated in the original Election/Restriction requirement Groups VI-VIII are drawn to tablets comprising Groups I-V (Group VI), process for manufacture of the tablets (Group VII), and methods of treatment comprising use of tablets (Group VIII). As explained in the Election/Restriction requirement, because Groups I-V are unrelated to Groups VI and VII, and the use of the product of Groups I-V to treat depression, Parkinson's disease, or psychotic disorders can be accomplished with another materially different product, such as tricyclic antidepressants, L-DOPA, and clozapine, respectively, there is undue burden of search on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections – 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. The claim should not refer to Figure 1, but should have the X-ray diffraction spectrum of Figure 1 within the claim itself.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapleo et al. (US Patent 4,818,764) in view of Conte (US Patent 5,487,901).

Chapleo et al. teach oral unit dosage forms of pharmaceutical compositions comprised of idazoxan hydrochloride, together with a pharmaceutically acceptable diluent or carrier (meeting the limitation of claims 1-2, 19) see whole document, in particular Example 1 and Claim 1).

Chapleo et al. does not teach a pharmaceutical composition comprised of microcrystalline cellulose, a lubricant, colloidal silica, or lactose.

Conte et al. teach pharmaceutical tablets capable of releasing active ingredients at subsequent times. The tablets contain excipients including microcrystalline cellulose (Col. 4, line 7) and colloidal silica (Col. 4, line 34), diluents such as lactose (Col. 4, line 29), and polymeric substances such as glyceryl behenate (Col. 4, line 59) further meeting the limitations of claim 1 and claim 18.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Chapleo et al., which teach idazoxan hydrochloride in a pharmaceutical composition, with the teachings of Conte et al. which teach pharmaceutical tablets comprised of the ingredients microcrystalline cellulose, colloidal silica, lactose and glyceryl behenate. One would have been motivated to add the ingredients of Conte et al. to the pharmaceutical composition of Chapleo et al. to facilitate a fast release of the drug into the system for treatment.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-6 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-8 of copending Application No. 10/974,675. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

Claims 1-6 and 18-19 are not allowed. Claims 32-34 are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER